UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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MARIA GIOIA,

Plaintiff,

-against-

JANSSEN PHARMACEUTICALS,

Defendant.
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For Online Publication Only

MEMORANDUM AND ORDER
19-CV-04629 (JMA) (SIL)
19-CV-05377 (JMA)(SIL)

APPEARANCES:

Maria Gioia
Pro se Plaintiff

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Attorneys for Defendant

AZRACK, United States District Judge:

Plaintiff Maria Gioia ("plaintiff"), acting pro se, commenced this diversity action on March 1, 2021 by filing an amended complaint against Janssen Pharmaceuticals ("defendant" or "Janssen"), manufacturers of the drug Invega. (Am. Compl., ECF No. 33.)[1] Plaintiff alleges that she suffered injuries because the defendant failed to properly warn of Invega's side effects. (Id.)

Before the Court is defendant's motion to dismiss the amended complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. (Def.'s Mot. to Dismiss, ECF No. 43.) For the reasons discussed below, defendant's motion is **GRANTED**.

[1] Plaintiff's amended complaint and the relevant motion papers were filed under docket numbers 19-CV-04629 and 19-CV-05377. For ease of reference, the Court refers only to the filings under docket number 19-CV-05377, unless otherwise noted, and cites to the Electronic Case Filing System ("ECF") pagination.

I. BACKGROUND

A. Procedural Background

Plaintiff commenced product liability actions on August 7, 2019 in Supreme Court, County of Nassau (19-CV-04629, "Gioia I"), and August 29, 2019 in Supreme Court, County of Suffolk (19-CV-05377, "Gioia II") against Janssen alleging lack of informed consent and failure to warn claims. Defendant removed Gioia I and Gioia II to this Court on the basis of diversity jurisdiction, pursuant to 42 U.S.C. § 1332, on August 12, 2019 and September 20, 2019, respectively. (Gioia I, Notice of Removal, ECF No. 1; Gioia II, Notice of Removal, ECF No. 1.) On February 16, 2021, this Court granted defendant's motion to dismiss plaintiff's lack of informed consent claim with prejudice and plaintiff's failure to warn claim without prejudice, granting plaintiff thirty days to amend the complaint. ("Dismissal Order," ECF No. 32.)

On March 1, 2021, plaintiff filed an unsigned amended complaint with exhibits. (Am. Compl.) On March 3, 2021, the clerk's office directed plaintiff to refile a signed copy of her amended complaint within fourteen days. (ECF No. 34.) Plaintiff refiled her signed amended complaint without exhibits on March 10, 2021. (ECF No. 35.) On April 30, 2021, defendant filed a fully briefed motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). (ECF Nos. 43-47.) On May 11, 2021, plaintiff filed an addendum to her opposition to defendant's motion to dismiss. (ECF No. 48.)

B. Factual Background[2]

Plaintiff's amended complaint alleges that defendant's failure to warn about the possible side effects of Invega led to her poor performance on medical board examinations and her ultimate ineligibility for a medical residency program. (Am. Compl. ¶¶ 1-3.) Plaintiff alleges that she

[2] The following facts are taken from the amended complaint and the record before the Court, including exhibits which are attached or integral to the amended complaint. See Sira v. Morton, 380 F.3d 57, 67 (2d Cir. 2004).

suffers from subclinical hypothyroidism, Horner's syndrome, facial nerve damage, motor tics, vocal tics, memory issues, confusion, loss of taste sensation and other feelings, PTSD, peripheral neuropathy, and metabolic syndrome, including hypertension, diabetes, and stroke. (Id. ¶¶ 1, 4-5.) Plaintiff's amended complaint seeks over sixteen million dollars in damages. (Id. at 3.)

II. DISCUSSION

A. Standard Under Rule 12(b)(6)

To survive a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a plaintiff must allege sufficient facts "to state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007). A claim is facially plausible only "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citing Twombly, 550 U.S. at 556). Mere labels and legal conclusions will not suffice. Twombly, 550 U.S. at 555. In reviewing a motion to dismiss, the Court must accept the factual allegations set forth in the complaint as true and draw all reasonable inferences in favor of the plaintiff. Cleveland v. Caplaw Enters., 448 F.3d 518, 521 (2d Cir. 2006). A court may also consider materials attached to the complaint, materials integral to the complaint, and materials incorporated into the complaint by reference. Sira, 380 F.3d at 67.

While a court is required to read a plaintiff's pro se complaint liberally and interpret it as raising the strongest arguments it suggests, a pro se plaintiff must still plead "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570; see also Harris v. Mills, 572 F.3d 66, 72 (2d Cir. 2009).

B. Jurisdiction

This Court has jurisdiction of plaintiff's state law claim based on diversity, pursuant to 28 U.S.C. § 1332. New York substantive state law applies to this diversity action. Principal Nat'l

Life Ins. Co. v. Coassin, 884 F.3d 130, 134 (2d Cir. 2018) ("Federal courts sitting in diversity cases will, of course, apply the substantive law of the forum State on outcome determinative issues.") (citation omitted).

For the foregoing reasons, the amended complaint fails to plead a sufficient claim against defendant. Therefore, defendant's motion to dismiss the amended complaint is granted.

C. Failure to Warn

In its prior Dismissal Order, the Court found that, "plaintiff's complaints provide only conclusory allegations that are insufficient to properly plead a failure to warn claim. Plaintiff fails to allege any facts to suggest that her treating physician was not informed of the risks associated with Invega." (Dismissal Order at 6.) Accordingly, in granting plaintiff leave to amend her failure to warn claim, the Court directed plaintiff to "provide non-conclusory allegations as to why defendant failed to provide adequate warnings to her physician." (Id. at 8.) Plaintiff's amended complaint fails to do so.

Under New York law, a pharmaceutical manufacturer satisfies its duty to warn of a product's risks "by providing information to the prescribing physician, not to the patient directly." Alston v. Caraco Pharm., Inc., 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009). The court should dismiss a failure to warn claim if "a plaintiff does not plead facts indicating how the provided warnings were inadequate." Reed v. Pfizer, Inc., 839 F. Supp. 2d 571, 575 (E.D.N.Y. 2012).

Plaintiff's amended complaint does not cure the deficiencies of her failure to warn claim because the amended allegations, like the original allegations, do not identify what warnings were provided to plaintiff's physician or how the provided warnings were inadequate. See Trisvan v. Heyman, 305 F. Supp. 3d 381, 399 (E.D.N.Y. 2018) (dismissing failure to warn claim where plaintiff "fail[ed] to provide any non-conclusory allegations to suggest that his treating physicians

were not informed of the potential side-effects of Risperdal and Wellbutrin"); Black v. Covidien, PLC, No. 17-CV-6085, 2018 WL 573569, at *3 (W.D.N.Y. Jan. 26, 2018) (dismissing failure to warn claim where plaintiff failed to "identify what warnings [d]efendant gave to plaintiff's physicians, how they were inadequate, or what warnings should have been given"). Rather, plaintiff makes only the conclusory allegation that Invega's website provided inadequate warnings about the drug's side effects (Amend. Compl. ¶ 1, Pl.'s Opp. at 4), but still fails to plead what warnings were given to her physician. As stated above, under New York law, "the manufacturer's duty to caution against . . . side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient." Green v. Covidien LP, 18-CV-2939, 2021 WL 1198833 at *9 (S.D.N.Y. March 30, 2021) (rejecting claim that product warnings must be included in marketing brochures or websites associated with such products) (citing Martin v. Hacker, 83 N.Y.2d 1, 9, (1993)). Thus, plaintiff's amended complaint fails to state a claim for failure to warn because it fails to allege any facts to suggest that her treating physician was not informed of the potential side-effects of Invega of which she complains. For this reason alone, plaintiff's conclusory allegations are insufficient to state a plausible failure to warn claim.

Moreover, nearly all of the alleged side effects plaintiff experienced are identified in Invega's FDA-approved package insert. (See Amend. Compl. ¶¶ 4-5; Russo Decl., ECF No. 45, Ex. A.)[3] "Courts have routinely held as a matter of law that a drug manufacturer will not be liable if there is evidence showing that the warning specifically warned of the side effects which occurred." Alston, 670 F. Supp. 2d at 286-87 (citing Wolfgruber, 423 N.Y.S2d 95). Therefore,

[3] The Court takes judicial notice of the FDA-approved package insert. See Becker v. Cephalon, Inc., No. 14-CV-3864, 2015 WL 5472311, at *3 (S.D.N.Y. Sept. 15, 2015) (taking judicial notice of FDA-approved labels in assessing failure to warn claim "because the labels can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.") (internal quotation marks omitted).

plaintiff's conclusory allegations coupled with plaintiff's allegations of suffering from the very side effects of which defendant warns, requires dismissal of plaintiff's claim.

Accordingly, defendant's motion is granted, and plaintiff's amended complaint is DISMISSED.

D. Leave to Amend

Federal Rule of Civil Procedure 15(a) (2) instructs courts to "freely give leave [to amend] when justice so requires." Courts must generally grant pro se litigants at least one opportunity to replead "'when a liberal reading of the complaint gives any indication that a valid claim might be stated.'" Thompson v. Carter, 284 F.3d 411, 416 (2d Cir. 2002) (quoting Branum v. Clark, 927 F.2d 698, 705 (2d Cir. 1991)). "Nonetheless, courts may deny leave to replead where amendment qualifies as futile." Herbert v. Delta Airlines, No. 12–CV–1250, 2014 WL 4923100, at *5 (E.D.N.Y. Sept. 30, 2014) (citing Cuoco v. Moritsugu, 222 F.3d 99, 112 (2d Cir. 2000)).

Here, the Court previously granted plaintiff leave to replead and identified the deficiencies of the original complaint. (See Dismissal Order at 8.) The amended complaint does not correct these deficiencies, and plaintiff's papers opposing the defendant's motion to dismiss provide no indication that further amendment would be successful. See Herbert, 2014 WL 4923100, at *5 (denying pro se plaintiff leave to amend where amended complaint failed to correct the deficiencies the court had previously identified); Alsaifullah v. Travis, 160 F. Supp. 2d 417, 421 (E.D.N.Y. 2001) ("[A]s the Amended Complaint, by definition, provided plaintiff a second chance to sufficiently plead the facts supporting this action, the court will not permit Plaintiff to replead."). Accordingly, the Court will not grant leave to replead again, and the amended complaint is **DISMISSED WITH PREJUDICE**.

III. CONCLUSION

For the reasons stated above, the defendant's motion to dismiss the plaintiff's amended complaint is granted and the plaintiff's amended complaint is dismissed with prejudice.

The Court certifies pursuant to 28 U.S.C. § 1915(a)(3) that, should she seek in forma pauperis status for the purpose of an appeal, any appeal from this order would not be taken in good faith and therefore in forma pauperis status is denied. See Coppedge v. United States, 369 U.S. 438, 444-45 (1962).

The Clerk of the Court is directed to send a copy of this Order to the pro se plaintiff.

SO ORDERED.

Dated: November 22, 2021
Central Islip, New York

/s/ (JMA)
JOAN M. AZRACK
UNITED STATES DISTRICT JUDGE